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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,625

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7504

7590 09/05/2008
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,625	Applicant(s) SHAH, KISHORE R.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,8-10,12-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-15,19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,8,10,16,18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to applicant's claims have been entered. Any rejection from the previous office action filed 03/06/2008 not addressed below has been withdrawn.

Response to Arguments

Applicant's arguments with respect to claims rejected over Morrissey from the previous office action have been considered and are persuasive since the Morrissey reference does not teach or reasonably describe a graft copolymer with a hydrophobic side chain consisting of polystyrene alone. However applicant's amendments to the claims have necessitated the new rejections below.

Claim Rejections - 35 USC § 112

Applicant's amendments to the claims necessitated this new rejection.

Claims 1-3,6,8,10,16,18,21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Firstly** independent claims 1,16 and 21 all contain the new limitation that the stable aqueous form of the copolymer is selected from the group consisting of a solution, an emulsion and a dispersion that forms at least one of a lotion, a cream, a gel, a petrolatum and a wax-based preparation, this new limitation does not have support within the specification. The groups above a solution, emulsion, dispersion, lotion, cream, gel, petrolatum and a

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wax-based preparation are all described within the specification (See [0014],[0024] and [0025] of applicants published specification) as being in the form of the bioadhesive, the specification never states that an emulsion, solution or dispersion form at least one of a lotion, cream, gel, petrolatum or a waxed based preparation. **Secondly** independent claims 1,16 and 21 recite that the bioadhesive is a homogeneous and stable aqueous form of a graft copolymer selected from a solution, an emulsion and a dispersion that forms at least one of a lotion, a cream, a gel, a petrolatum and a wax-based preparation, this new limitation does not have support within the specification. Within applicants specification the only form that is described as a homogeneous and stable aqueous form is a gel, applicants did not describe the other claimed forms including an emulsion or solution that is in a homogeneous and in a stable form (See [0024] and [0025] of applicants published specification). **Thirdly** claim 21 states that the composition which is in the form of an emulsion, solution or gel is homogenized, however the specification only describes homogenation when referring to the gel, emulsion and cream or lotion formulations. To expedite the examination process the examiner considered any solution, emulsion, dispersion, lotion, cream, gel, petrolatum or wax-based preparation containing the same copolymer as claimed as meeting applicants claimed limitations.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,16 and 21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. All of the above claims state that a homogeneous and stable aqueous form of a graft copolymer selected from the group consisting of a solution, an emulsion and a dispersion, as the claim currently reads it appears from the language that the polymer is a stable and aqueous form selected from a solution, emulsion or dispersion. Of course copolymers cannot be considered as being in any of the above physical forms by itself rather it is the composition to which applicants are referring to when they describe a homogeneous and stable aqueous solution, emulsion or dispersion. **Secondly** claim 21 states in step (b) that the composition is homogenized until it forms a stable dispersion, however a dispersion was only one of the types of forms defined within the same claim at lines 3-5. Thus the claim is indefinite with respect to if the step of homogenation is only a step for the dispersion or for all of the types of forms encompassed by the claims (emulsion, solution ect). **Thirdly** it is not clear how an emulsion and dispersion can be considered homogeneous when they are by definition comprised of at least two separate phases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,6,8,16,18,21-23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah (US 5,942,243, cited previously). This new rejection was necessitated by applicant's amendments to the claims. It is noted by the examiner that

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the anticipatory rejection over Shah was previously withdrawn, however applicants amendments to the claims now broaden the scope of the claimed composition to include the forms of solution, emulsion as well as previously claimed dispersion. Since the Shah reference teaches aqueous solutions of applicants claimed copolymers as outlined below it is once again considered prior art.

Shah teaches mucoadhesive compositions comprising graft copolymers containing 1-20% of a polystyrene macromonomer side chain and 80-99% of a hydrophilic acidic backbone. See abstract, col 2 lin 53-col 3 lin 56. Shah also teaches that the compositions can be in several different forms including ointments, solutions and dispersions. The amount of copolymer within the formulations of the examples was within applicants claimed amount of about 0.3 to about 10%. From example 6 the graft copolymer was mixed with equal amount of PEG to form film and 1.3 g of the film was dissolved in 6.1 ml (6.1 g) of water, therefore $0.65\text{g graft copolymer} / 7.4\text{ g total} \times 100 = 8.7\%$. See examples especially example 6. Also Shah specifically recites within example 10 that the aqueous solution of graft copolymer from example 7 was added to Poly(acrylic acid) and mixed with a spatula and allowed to stand overnight until it had become **a homogeneous almost clear solution**. Since the solution was stirred and left to stand until it formed a clear homogeneous aqueous solution the limitation within claim 21 part b is considered met. Regarding the limitations that the composition contains a biologically active agent, Shah specifically recites that the mucoadhesive composition can be used as a drug delivery vehicle. See col 5 lin 57-col 6 lin 63.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3,6,8,10,16,18,21-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Milkovich et al. (US 4,085,168), this new rejection was necessitated by applicants amendments to the claims.

Milkovich describes water-dispersible and water-swellaable graft copolymers comprised of a hydrophilic backbone and a hydrophobic side chain, within the examples a graft copolymer of 80% Polyacrylic acid as the backbone and 20% polystyrene as the side chain was used. See abstract, col 3 lin 44-col 4 lin 32, col 6 lin 54-60 and examples, especially 15-17 and 26. The copolymers were said to be able to be adapted for use as a carrier for a medicinally active substance. Water was added to the copolymers to form both a gel and an emulsion. See co 35 lin 12-col 36 lin 31. Milkovich while disclosing emulsions and gels comprising the graft copolymer does not describe an amount of copolymer within the composition that falls within applicants claimed

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amount (about 0.3 to about 10%). However Milkovich does describe that the aqueous liquid can be added in amounts of preferably more than 95% by weight of the composition, thus it would have been obvious to one of ordinary skill in the art that small amounts of the copolymer could be employed while still retaining the gels characteristics. One of ordinary skill in the art would have good reason through normal and routine experimental optimizations to find the amount of copolymer and liquid concentrations that yielded the most desirable properties for the intended use of the composition. Thus applicants claimed invention was prima facie obvious in view of the disclosure of the Milkovich reference.

Claims 1-3,6,8,10,16,18,21-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Shah (US 5,942,243), this new rejection was necessitated by applicants amendments to the claims.

Shah is disclosed above. Shah while disclosing emulsions and gels comprising the graft copolymer does not describe an amount of copolymer within the composition that falls within applicants claimed amount for some of the dependent claims (about 0.3 to about 5% and about 0.3 to about 3%). However Shah does describe that the aqueous liquid can be added in amounts of preferably more than 95% by weight of the composition, thus it would have been obvious to one of ordinary skill in the art that small amounts of the copolymer could be employed while still retaining the compositions characteristics. One of ordinary skill in the art would have good reason through normal and routine experimental optimizations to find the amount of copolymer and liquid concentrations that yielded the most desirable properties for the intended use of the

composition. Thus applicants claimed invention was prima facie obvious in view of the disclosure of the Shah reference.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618